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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/579,327	05/25/00	RIORDAN	N RIORD.004A

EXAMINER	
FIELDS, I	
ART UNIT	**PAPER NUMBER**
1645	9

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DATE MAILED: 10/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/579,327	RIORDAN ET AL.	
	Examiner	Art Unit	
	Iesha P Fields	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-21 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Applicant's Amendment filed July 30, 2001 (Paper No 8) has been received and entered. Claims 13 and 21 have been amended consequently claims 1-21 are pending in the instant application.

Response to Amendment

The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 112

1. Claims 1-21 rejected under 35 U.S.C. 112, second paragraph, as being vague in recitation of "acceptable pH" is **maintained**.

Applicant has asserted that one of ordinary skill in the art would know what constitutes a physiologically acceptable pH.

Applicant's arguments have been fully and carefully considered and they are not deemed to be persuasive.

As the applicant has indicated in the response to the rejection, the pH could vary depending on the mode of administration. According to the applicant the pH could be "about 1.5 to 2.5 or more". One of skill in the art would be unable to determine the metes and bounds of the limitations. As stated previously, without clear guidance as to

the exact pH encompassed by the claimed invention one would be forced into undue experimentation and could not replicate the claims.

Claim Rejections - 35 USC § 102

2. Claims 1-4, 6, 8-9, and 14 rejected under 35 U.S.C. 102(b) as being anticipated by Matsuzaki et al. is **maintained**.

Applicant has asserted that the claimed invention is a method for making peptidoglycan extracts by treating them with an "acid". Applicant's have further asserted that Matsuzaki et al. teaches of making peptidoglycan extracts using an enzyme and therefore does not anticipate the claimed invention.

Applicant's arguments have been fully and carefully considered and they are not deemed to be persuasive.

Matsuzaki et al. disclose a method for making peptidoglycan extracts. Matsuzaki et al. further disclose a method for making peptidoglycan extracts comprising the use of hydrochloric acid at a pH of 8.0 (See Summary of the Invention; Especially Column 2).

Claim Rejections - 35 USC § 103

3. Claims 1, 11-12, 16 and 19 rejected under 35 U.S.C. 103(a) as being unpatentable over Matsuzaki et al. in view of Converse et al. is **maintained**.

Applicant has asserted that Matsuzaki et al. teaches of making peptidoglycan extracts using an enzyme. Applicant has further asserted that Converse et al. teaches of removing lipids using chloroform.

Applicant's arguments have been carefully considered but not deemed persuasive.

Claim 12 recites a method of removing lipids using chloroform. The Examiner agrees with the applicant that Converse et al. teaches of removing lipids using chloroform and therefore teaches the limitation recited in claims 11-12. As stated above, Matsuzaki et al. discloses a method for making peptidoglycan extracts using an acid (HCl).

Claim Rejections - 35 USC § 103

4. Claims 1, 4-5, 7, 10, 13, 15-17, and 20-21 rejected under 35 U.S.C. 103(a) as being unpatentable over Matsuzaki et al. in view of Converse and Roe et al. is **maintained**.

Applicant's have asserted that neither Matsuzaki or Converse et al. teach of using an acid to produce a cell wall extract. Applicant's have further asserted that the prior art teaches of standard techniques such as heat treatment and denaturation with strong acids such but does not teach of the production of an immunologically active extract by hydrolyzing peptidoglycan bonds.

Applicant's arguments have been fully and carefully considered and they are not deemed to be persuasive.

The claims are drawn to a method of making a peptidoglycan extract from bacteria comprising heat treatment, ultrafiltration, and treatment with acetic acid.

As stated above, Matsuzaki et al. discloses a method for making peptidoglycan extracts using an acid. Roe et al. teach of standard techniques used in protein purification. The standard techniques include heat treatment (i.e. high temperatures), denaturation by extremes of pH and treatment with strong acids such as acetic acid and TCA. (See especially sections 66.1-66.3). Roe et al. further teach of several filtration methods (See especially chapter 3).

Given that 1) Matsuzaki et al. has taught of a method of making a peptidoglycan extract from *Lactobacillus fermentum* and that 2) Converse et al. has taught of a method of extracting lipids from a solution and that 3) Roe et al. has taught of standard techniques used in protein purification it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make a peptidoglycan extract from bacteria employing standard purification techniques. One would have been motivated to employ techniques such as heat treatment, ultrafiltration, and treatment with a strong acid because such techniques are well known purification techniques.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

For the above reasons, it is believed that the rejections should be sustained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iesha P Fields whose telephone number is (703) 605-1208. The examiner can normally be reached on 7am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Iesha Fields

October 17, 2001

MARK NAVARRO
PRIMARY EXAMINER